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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,211	04/09/2001	Hideshi Fujiwake	P107331-00009	3660

7590

10/25/2002

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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 10/25/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/828,211

Applicant(s)

FUJIWAKE, HIDESHI

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☒ Other: *Notice to Comply*.

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***Response to Amendment***

1. The amendment filed 7/25/2002 has been entered.
2. The rejection of claims 1-6 under 35 U.S.C. §112, second paragraph is withdrawn.
3. The rejection of claims 1 and 3 under 35 U.S.C. §102(b) anticipated by Oefner et al. (5,795,976) is withdrawn.
4. The rejection of claims 2 and 4-6 under 35 U.S.C. §103(a) over Oefner et al. (5,795,976) as applied to claims 1 and 3 above, and further in view Diamond et al. (6,265,557) is withdrawn.

***NEW GROUNDS OF REJECTIONS***

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oefner et al. (5,795,976) in view of Schultz et al. (6,268,146).

Oefner et al. disclose a method of separating heteroduplex and homoduplex DNA molecules in a mixture and the mixture is applied to a stationary reverse phase support. The method has many applications including identification of gene mutations (See the Abstract and

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column 4, lines 53-62). The method involves amplifying the mixture by using polymerase chain reaction (See column 5, lines 55-60). The method can be used for a base pair mismatch and or an insertion/deletion in the sample fragments (See column 6, lines 34-45). The base pair mismatch refers to a single base pair mismatch flanked by matched base-pairs and includes a series of mismatched base-pairs flanked by matched base-pairs (See column 9, lines 22-26). This *does it mean multiple mismatched* teachings suggest that the mismatch can be multiple mismatches in a single target nucleic acid sequence.

Oefner et al. do not disclose using a plurality of labeled oligonucleotide probes to detect multiple mismatches on a single stranded target nucleic acid.

Schultz et al. disclose that the method can be used for identifying single base changes (See the Abstract). The method of Schultz et al. involves a plurality of different nucleic acid probes, preferably after amplification of the multiple nucleic acid targets (See column 15, lines 1-5 and 30-35, and column 15, lines 58-63). The probes are labeled with fluorescence (See column 18, lines 25-42) in which different fluorescent labels are used (See column 18, lines 52-60).

Thus, one of ordinary skill in the art at the time of the instant would have been motivated to modify the method of Oefner et al. by using plurality of probes with various fluorescence labels as taught by Schultz et al. to detect a multiple mismatches in a single target nucleic acid sequence with a reasonable expectations of success because the method of Schultz et al. can be used for detecting mutations in which the sensitivity is very high level without the need for

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radiochemical or electrophoresis (See column 7, lines 7-10 and lines 20-26). Thus, it would have been prima facies obvious to carry out the method as claimed.

***Sequence Rules***

7. The CRF diskette filed on 7/25/2002 is not fully responsive to the communication mailed 4/24/2002 for the reason(s) set forth on the attached Notice of Comply With the Sequence Rules or CRF Diskette Problem Report.

Since the response appears to be bona fide, but through an apparent oversight or inadvertence failed to provide a complete response, applicant is required to complete the response withing the response period set forth in this Office action.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

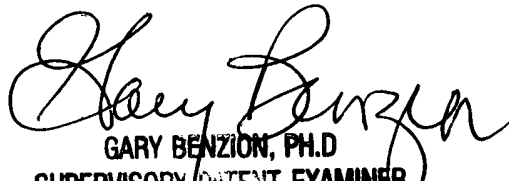
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

October 7, 2002

  
GARY BENZION, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600